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PATENT & TRADEMARK OFFICE

9-23-04 DPW 1651

Express Mail No.: EV 544892821 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Dingivan *et al.*

Application No.: 10/091,236

Filed: March 4, 2002

For: METHODS OF PREVENTING OR TREATING INFLAMMATORY OR AUTOIMMUNE DISORDERS BY ADMINISTERING INTEGRIN ALPHANUBETA3 ANTAGONISTS IN COMBINATION WITH OTHER PROPHYLACTIC OR THERAPEUTIC AGENTS

Confirmation No.: 7180

Group Art Unit: 1651

Examiner: To Be Assigned

Attorney Docket No.: 10271-053-999

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references **B01** to **B17** and **C01** to **C76** listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." Copies of references **B01** to **B17** and **C01** to **C76** are submitted herewith.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application. While not to be construed as indicating that the Examiner should not review and consider fully all of the listed references, Attorneys for Applicants particularly direct the Examiner's attention to references B01, B04-B06, B09-B11, B14, B16, C12, C13, C19, C22, C28, C35, C45, C52, C70, C72, C74 and C75.

Pursuant to 37 C.F.R. § 1.97(b)(3), Applicants estimate that no fee is due in connection with the filing of this Information Disclosure Statement. However, should the Patent Office determine otherwise, please charge the necessary fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

Date September 22, 2004

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Enclosures

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ATTY. DOCKET NO.	APPLICATION NO.
10271-053-999	10/091,236
APPLICANT	
Dingivan and Wilder	
FILING DATE	GROUP
March 4, 2002	1651

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	WO 03/075957	9/18/03	PCT				
	B02	WO 03/0068320	4/10/03	PCT				
	B03	WO 03/0044406	3/6/03	PCT				
	B04	WO 02/069904	9/12/02	PCT				
	B05	WO 00/78815	12/28/00	PCT				
	B06	WO 00/78814	12/28/00	PCT				
	B07	WO 00/31248	6/2/00	PCT				
	B08	WO 99/03502	1/28/99	PCT				
	B09	WO 98/46264	10/22/98	PCT				
	B10	WO 98/40488	9/17/98	PCT				
	B11	WO 98/33919	8/6/98	PCT				
	B12	WO 98/23289	6/4/98	PCT				
	B13	WO 97/34631	9/25/97	PCT				
	B14	WO 95/25543	3/9/95	PCT				
	B15	WO 93/08656	4/29/93	PCT				
	B16	WO 89/05155	6/15/89	PCT				
	B17	EP 555880	8/18/93	EP				

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	C01	GenBank AF018081 Human type XVIII collagen (COL18A1) m RNA, alternatively spliced, long form, complete cds
	C02	GenBank AF018082 Human type XVIII collagen (COL18A1) m RNA, alternatively spliced, short form, complete cds
	C03	GenBank AH002740 human T-cell surface antigen T11 (CD2) gene, exon 1, clone PB2
	C04	GenBank CAA29622
	C05	GenBank E12817 cDNA encoding human LFA-3
	C06	GenBank M16445 human surface antigen CD2 mRNA, complete cds
	C07	GenBank NM_000301 human plasminogen (PLG), mRNA

	C08	GenBank X06143 murine mRNA for T11 protein
	C09	Abrams et al., 2000, "Blockade of T lymphocyte costimulation with cytotoxic T lymphocyte-associated antigen 4-immunoglobulin (CTLA4Ig) reverses the cellular pathology of psoriatic plaques, including the activation of keratinocytes, dendritic cells, and endothelial cells," J. Exp. Med. 192(5):681-694
	C10	Adkins et al., 2000, "A phase I placebo-controlled, randomized, dose-escalation safety study of MEDI-507, a humanized anti-CD2 monoclonal antibody, in the initial treatment of at least grade II acute graft-versus-host disease," Itinerary for the American Society of Hematology 42nd Annual Meeting 12/4/00, Blood 96:476A Poster Board No. 784
	C11	Ashcroft et al., 2000, "Therapeutic strategies for psoriasis," J. Clin. Pharm. Ther. 25(1):1-10
	C12	Ashkenazi et al., 1991, "Protection against endotoxic shock by a tumor necrosis factor receptor immunoadhesin," Proc. Natl. Acad. Sci. USA 88:10535-10539
	C13	Bathon et al., 2000, "A comparison of etanercept and methotrexate in patients with early rheumatoid arthritis," N. Eng. J. Med. 343:1586-1593
	C14	Besse et al., 1997, "Prevention of rejection with BTI-322 after renal transplantation (Results at 9 months)," Transplantation Proc. 29:2425-2426
	C15	Branco et al., 1999, "Selective deletion of antigen-specific, activated T cells by a humanized MAB to CD2 (MEDI-507) is mediated by NK cells," Transplantation 68(10):1588-1596
	C16	Chisholm et al., 1994, "The effects of an immunomodulatory LFA3-IgG_1 fusion protein on nonhuman primates," Therapeutic Immunity 1:205-216
	C17	Cockett et al., 1990, "High level expression of tissue inhibitor of metalloproteinases in Chinese hamster ovary cells using glutamine synthetase gene amplification," Biotechnology 8:662-667
	C18	Couriel et al., 2000, "Infliximab for the treatment of graft-versus host disease in allogenic transplant recipients: an update," Itinerary for the American Society of Hematology 42nd Annual Meeting, 12/4/00, Poster board Number 775
	C19	Davis et al., 1996, "The structure and ligand interactions of CD2: Implications for T-cell function," Immunology Today 17(4):177-187
	C20	Dehoux et al., 2000, "Effects on human and nonhuman primate immune response of a new rat anti-CD2 monoclonal antibody," Transplantation 69(12):2622-2633
	C21	De La Parra et al., 1991, "Inhibition of T-Cell Activation by Lo-CD2-a, A rat monoclonal antibody against the human CD2 glycoprotein," Belgian Journal of Zoology 121(Supp. 1):13 Abstract 16
	C22	Diasio et al., 1996, "Immunomodulators: Immunosuppressive agents and immunostimulants," in: The Pharmacological Basis of Therapeutics, McGraw-Hill, New York, Ch. 52, pp. 1291-1306
	C23	Disepio et al., 2000, "New drugs in the treatment of psoriasis," Expert Opin. Investig.

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PATENT & TRADEMARK OFFICE

		Drugs 9(1):79-93
	C24	Dumont et al., 1998, "Potent apoptotic signaling and subsequent unresponsiveness induced by a single CD2 mAb (BTI-322) in activated human peripheral T cells," J. Immunol. 3797-3804
	C25	Durie et al., 1994, "The role of CD40 in the regulation of humoral and cell-mediated immunity," Immunol. Today 15(9):406-411
	C26	Ellis, 1999, "Quality of Life (QOL) of Amevive™ (LFA3TIP) in patients with chronic plaque psoriasis," Amevive Breakfast Meeting, 12/3/99 and abstract from Br. J. Dermatol. 141:990 Abstract 82
	C27	Ellis et al, "Quality of Life (QOL) in patients with chronic plaque psoriasis treated with Amevive (LFA3TIP)," Poster Presentation
	C28	Feldmann et al., 1999, "Cytokine Inhibitors: Biologics," Inflammation: Basic Principles and Clinical Correlates, 3rd ed., Gallin and Snyderman, eds. Lippincott, Williams, & Wilkins, Philadelphia, pp. 1207-1212
	C29	Ferrant et al., 1997, "LO-CD2a/BTI322 for steroid resistant graft-versus host disease," BTI Ref. 1979 Transplant 19(Supp. 1):S181 Abstract P721
	C30	Fredriksson and Pettersson, 1978, "Severe psoriasis - oral therapy with a new retinoid," Dermatologica 157(4):238-244
	C31	Griffiths, 1999, "T cell targeting for psoriasis," Amevive Breakfast Meeting 12/3/99
	C32	Jooss et al., 1996, "Cyclophosphamide diminishes inflammation and prolongs transgene expression following delivery of adenoviral vectors to mouse liver and lung," Hum. Gene Ther. 7:1555-1566
	C33	Kaplon et al., 1996, "Short course single agent therapy with an LFA-3-IgG_1 fusion protein prolongs primate cardiac allograft survival," Transplantation 61(3):356-363
	C34	Kohno et al., 1990, "A second tumor necrosis factor receptor gene product can shed a naturally occurring tumor necrosis factor inhibitor," Proc. Natl. Acad. Sci. USA 87:8331-8335
	C35	Kozarsky et al., 1993, "An anti-CD2 monoclonal antibody that both inhibits and stimulates T cell activation recognizes a subregion of CD2 distinct from known ligand-binding sites," Cell Imunol. 150(2):235-246
	C36	Krogh et al., 1999, "Models to study the pathogenesis of thyroid autoimmunity," Biochimie 81:511-515
	C37	Krueger et al., 2000, "Anti-CD11a treatment for psoriasis concurrently increases circulating T-cells and decreases plaque T-cells, consistent with inhibition of cutaneous T-cell trafficking," J. Invest. Dermatol. 115(2):333
	C38	Krueger, 1999, "Efficacy and safety results of a phase II trial with LFA3TIP in patients with chronic plaque psoriasis," Amevive Breakfast Meeting 12/3/99
	C39	Krueger, 1999, "Phase II trial results of Amevive™ (LFA3TIP) in patients with chronic plaque psoriasis," Br. J. Dermatol. 141:979-980, Abstract 39

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	C40	Krueger et al., 2000, "Successful in vivo blockade of CD25 (High-affinity interleukin 2 receptor) on T-cells by administration of humanized anti-Tac antibody to patients with psoriasis," J. Am. Acad. Dermatol. 43(3):448-458
	C41	Latinne et al., 1996, "An anti-CD2 mAb induces immunosuppression and hyporesponsiveness of CD2+ human T cells in vitro," Int. Immunol. 8(7):1113-1119
	C42	Lerut et al., "The use of tacrolimus (TAC) and anti-CD2 antibody Lo-CD2a (BTI-322) in adult liver transplantation (LT): Preliminary results of a prospective randomized study," Abstract 102
	C43	Li et al., 1995, "CD2 Antigen: Signaling features and strategies to inhibit CD2 antigen-derived signals," in Recent Devel. Trans. Med. Vol. 2, Ch. 7, Salomon and Sollinger, eds., pp. 97-121
	C44	Linden et al., 1999, "Psoriasis: Current perspectives with an emphasis on treatment," Am. J. Med. 107(6):595-605
	C45	Lipsky et al., 2000, "Infliximab and methotrexate in the treatment of rheumatoid arthritis," N. Enlg. J. Med. 343(22):1594-1602
	C46	Lopez-Berestein et al., 1989 in: Liposomes in the Therapy of Infectious Disease and Cancer, Lopez-Berestein and Fiedler, eds., Alan R. Liss, NY, pp. 353-365 or 317-327
	C47	Magilavy et al., "Immunopharmacologic effects of AMEVIVE™ (LFA3TIP) in chronic plaque psoriasis: Selectivity for peripheral memory effector (CD45RO+) over naïve (CD45RA+) T cells," Poster presentation and abstract from Br. J. Dermatol. 141:990, Abstract 81
	C48	Magilavy et al., 2000, "The Response of Plaque Psoriasis to AmeviveTM (LFA3TIP)and the Selective Suppression of Memory/Effector T Cells (CD45RO+) Verses Naïve T Cells (CD45RA+) Is Serume Levels of LFA3TIP," J. Invest. Dermatol. 114(4):776 Abstract 148
	C49	Magilavy et al., 1999, "Pharmacodynamic effects of Amevive™ (LFA3TIP), a LFA-3/igg Fc fusion protein in chronic plaque psoraisis: selectivity for peripheral memory-effectory (CD45RO+) over naïve (CD45RA+) T cells," Ameveive Breakfast Meeting, 12/3/99
	C50	Majeau et al., 1994, "Mechanism of Lymphocyte Function-Associated Molecule 3-Ig Fusion Proteins Inhibition of T Cell Responses," J. Immunol. 152(6):2753-67
	C51	Meier et al., 1995, "Immnonomodulation by LFA3TIP, an LFA-3/IgG1 Fusion Protein: Cell Line Dependent Glycoslyation Effects on Pharmacokinetics and Pharamcodynamic Markers," Ther. Immunol. 2(3):159-171
	C52	The Merck Manual of Diagnosis and Therapy, 1999, 17th ed., Beets and Berkow, eds., Merck Research Laboratories, Whitehouse Station, NJ pp. 416-423
	C53	Miller et al., 1993, "Specific Interaction of Lymphocyte Function-Associated Antigen 3 with CD2 Can Inhibit T Cell Responses," J. Exp. Med. 178:211-222
	C54	Mollereau et al., 1999, "Effects of Anti-CD2 Monoclonal Antibody: CD2- and CD95-Mediated Apoptosis of Human Peripheral T Cells," Transplantation Proc. 31:1245

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	C55	Mourad et al., 1997, "BTI-322 for Acute Rejection After Renal Transplantation," Transplantation Proc. 29:2353
	C56	Nizet et al. 2000, "The experimental (in vitro) and clinical (in vivo) immunosuppressive effects of a rat IgG2b anti-human CD2 mAb, LO-CD2a/BTI-322," Transplantation 69(7):1420-1428
	C57	Order et al., eds., 1985, "Analysis and future prospective of the therapetic use of radiolabeled antibody in cancer therapy," in: Monoclonal Antibodies for Cancer Detection and Therapy, Academic Press, pp. 303-316
	C58	Oswald et al., 1992, "Interleukin 10 inhibits macrophage microbicidal activity by blocking the endogenous production of tumor necrosis factor alpha required as a costimulatory factor for interferon gamma-induced activation," Proc. Natl. Acad. Sci. USA 89:8676-8680
	C59	Paul, ed., 1989, Fundamental Immunology 2nd Ed., Raven Press, NY, pp. 332-336
	C60	Peters et al., 2000, "Pathophysiology and treatment of psoriasis," Am. J. Health Sys. Pharm. 57(7):645-659
	C61	Przepiorika et al., "Pharmacokinetics and Safety of BTI-322, a Rat Anti-CD2 Monoclonal Antibody for Treatment of Steroid-Resistant Acute Graft-Versus-Host Disease," BTI Ref 3623
	C62	Przepiorka et al., 1998, "A Phase II Study of BTI-322, a Monoclonal Anti-CD2 Antibody, for Treatment of Steroid-Resistant Acute Graft-Versus-Host Disease," Blood 92(11):4066-4071
	C63	Rabinowitz et al., 1995, "In vitro activation leads to the binding of T-cell markers to the surface of B-lymphocytes," Clin. Immunol. Immunopathol. 76(2):148-154
	C64	Ratanathatathorn et al., 1999, "Pharmacokinetics and Safety of Medi-507, a Humanized Anti-CD2 Monoclonal Antibody in Severe Steroid-Resistant Graft-Versus-Host Disease," International Society for Experimental Hematology, Abstract 119
	C65	Roenigk et al., 1988, "Methotrexate in psoriasis: revised guidelines," J. Am. Acad. Dermatol. 19(1 pt. 1):145-156
	C66	Rosenberg and Gallin, 1999, "Inflammation," in: Fundamental Immunology 4th Ed., Paul, ed., Lippincott-Raven Publishers, Phila., pp. 1051-1066(Chapter 32)
	C67	Rouleau et al., 1997, "CD2 Induced Apoptosis of Peripheral T Cells," Transplantation Proc. 29:2377-2378
	C68	Schad et al., 1996, "An Anti-CD2 Monoclonal Antibody That Elicits Alloantigen-Specific Hyporesponsiveness," Transplantation Proceedings 28(4):2051-2053
	C69	Seckinger et al., 1990, "Characterization of a tumor necrosis factor alpha (TNF-alpha) inhibitor: evidence of immunological cross-reactivity with the TNF receptor," Proc. Natl. Acad. Sci. USA 87:5188-5192
	C70	Sultan et al., 1997, "Blockade of CD2-LFA-3 Interactions Protects Human Skin Allografts in Immunodeficient Mouse/Human Chimeras," Nature Biotechnology 15:759-762

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	C71	Thorbecke et al., 1992, "Involvement of endogenous tumor necrosis factor alpha and transforming growth factor beta during induction of collagen type II arthritis in mice," Proc. Natl. Acad. Sci. USA 89:7375-7379
	C72	Vie et al., 1992, "Human fusion proteins between interleukin 2 and IgM heavy chain are cytotoxic for cells expressing the interleukin 2 receptor," Proc. Natl. Acad. Sci. USA 89(23):11337-11347
	C73	Williams et al., 1994, "Synergy between anti-CD4 and anti-tumor necrosis factor in the amelioration of established collagen-induced arthritis," Proc. Natl. Acad. Sci. USA 91:2762-2766
	C74	Wu et al., 1998, "Stepwise in vitro affinity maturation of Vitaxin, an alphav beta3-specific humanized mAb," Proc. Natl. Acad. Sci. USA 95(11):6037-6042
	C75	Xu et al., 2000, "Inhibition of Human Anti-Pig T Cell Response by Anti-CD2, Anti-CD40L, and CTLA4-Ig: A Comparative Study," Transplantation Proc. 32:926
	C76	Yokota et al., 1986, "Isolation and characterization of a human interleukin cDNA clone, homologous to mouse B-cell stimulatory factor 1, that expresses B-cell- and T-cell-stimulating activities," Proc. Natl. Acad. Sci. USA 83:5894-5898

EXAMINER	**DATE CONSIDERED**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.